Complete Summary

GUIDELINE TITLE

The role of endoscopy in dyspepsia.

BIBLIOGRAPHIC SOURCE(S)

Eisen GM, Dominitz JA, Faigel DO, Goldstein JA, Kalloo AN, Petersen BT, Raddawi HM, Ryan ME, Vargo JJ 3rd, Young HS, Fanelli RD, Hyman NH, Wheeler-Harbaugh J. The role of endoscopy in dyspepsia. Gastrointest Endosc 2001 Dec; 54(6):815-7. [24 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Dyspepsia

DISCLAIMER

Note: Dyspepsia is defined as a constellation of symptoms that include upper abdominal pain or discomfort, which is intermittent or constant and may be associated with additional symptoms of nausea and vomiting. Although these symptoms may be associated with a wide range of specific clinical diagnoses (peptic ulcer disease [PUD], gastric cancer, and gastroesophageal reflux disease [GERD], among others), often no organic cause can be found (functional dyspepsia).

GUIDFLINE CATEGORY

Diagnosis Evaluation Management Risk Assessment

CLINICAL SPECIALTY

Gastroenterology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To define the role of upper endoscopy in the diagnostic evaluation and management of patients with dyspepsia

TARGET POPULATION

Patients with dyspepsia

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Upper endoscopy
- 2. Physical examination
- 3. Biopsy
- 4. Helicobacter pylori testing
- 5. Upper gastrointestinal (UGI) barium studies (considered, but not recommended)

Management/Treatment

- 1. Acid suppressive agents
- 2. Prokinetic agents
- 3. Empiric Helicobacter pylori "testing and treating" strategy
- 4. Discontinuation of ulcerogenic medications (e.g., nonsteroidal anti-inflammatory agents [NSAIDs]), cigarettes, and alcohol
- 5. Upper endoscopy

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Quality of life
- Signs and symptoms

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Dyspepsia is defined as a constellation of symptoms that include upper abdominal pain or discomfort, which is intermittent or constant and may be associated with additional symptoms of nausea and vomiting. Although these symptoms may be associated with a wide range of specific clinical diagnoses (peptic ulcer disease [PUD], gastric cancer, and gastroesophageal reflux [GERD], among others), often no organic cause can be found (functional dyspepsia). High-risk patients (as defined below) present with additional signs and symptoms, so-called "alarm symptoms," suggestive of more significant organic causes. In the absence of such "alarm symptoms," provisional diagnoses based on history and physical examination alone are often inaccurate, leading to inappropriate management plans and/or a delay in establishing the correct diagnosis. Endoscopic examination of the upper gastrointestinal tract remains the "gold standard" for establishing (or excluding) PUD and other specific organic diseases or upper gastrointestinal (UGI) pathologies. Endoscopy is the procedure of choice for the diagnostic evaluation of the UGI tract because of its ease, reliability, diagnostic superiority, and the ability it gives the endoscopist to perform biopsies and/or therapeutic interventions. This is especially true for patients presenting with dyspepsia and patients who are at high risk based on the presence of additional symptoms, physical signs, or both. These high-risk patients include the following:

- 1. Patients over 50 years old with new-onset dyspepsia
- 2. Those with dyspepsia associated with dysphasia and/or weight loss
- 3. Those with evidence of gastrointestinal bleeding (occult blood, anemia, hematemesis, and/or hematochezia/melena)
- 4. Those who have not responded to an appropriate trial of empiric therapy
- 5. Those patients using nonsteroidal anti-inflammatory drugs (NSAIDs) or other ulcerogenic agents
- 6. Those with signs or symptoms of UGI tract obstruction (e.g., early satiety, vomiting)
- 7. Those whose ethnic and/or racial background is associated with increased risk for UGI malignancies or other significant disease states

In the absence of these high-risk signs and symptoms, alternative nonendoscopic strategies for initial management of patients with dyspeptic symptoms have been advocated by some. However, based on marginal (if any) medical benefit, long-term cost-effectiveness has not been established. These strategies include (1)

empiric therapy with acid suppression or prokinetic agents, or (2) an empiric Helicobacter pylori "testing and treating" strategy. Based on current evidence, no single strategy, including early endoscopy, has been demonstrated to be more medically effective than any other. There is uncertainty about the rates of clinical improvement (effectiveness) with nonendoscopic management (empiric treatment). It is equally unclear how many patients will ultimately need/undergo endoscopy to evaluate empiric treatment failures or relapse. Because these rates have a large impact on economic and patient quality-of-life outcomes, there remains uncertainty in their net benefit.

Whether Helicobacter pylori plays a causative role in dyspepsia (and nonulcer dyspepsia) remains controversial. Many patients with new-onset dyspepsia as an isolated symptom (epigastric pain/discomfort without weight loss, evidence of gross or occult bleeding, obstruction, perforation, or associated multisystem disease) may be treated empirically for H pylori based on a positive test result for H pylori. This is more commonly accepted for younger individuals (e.g., <45-50 years old). However, for patients >50 years old or any patients with the risk factors listed above, endoscopy should be the first-line approach. It is important to recognize that these guidelines for H pylori "test and treat" must remain fluid and that certain populations are at higher risk for H pylori-associated PUD and/or gastric cancer. As such, patients at higher risk of PUD or UGI malignancies based on ethnic, racial, or socioeconomic status may prompt an endoscopy as a first-line intervention to confirm/exclude the diagnosis and to institute definitive and directed therapies.

In the absence of high-risk factors, empiric therapy may include either a "test and treat" strategy for Helicobacter pylori or alternatively an empiric trial of acid-suppressive agents and/or prokinetic agents for 4 to 8 weeks. Offending agents (e.g., nonsteroidal anti-inflammatory drugs, other ulcerogenic medications, cigarettes, and alcohol) should also be withdrawn. Implied in either empiric strategy is that a diagnostic endoscopy will be performed if there is a failure to alleviate symptoms because a definitive diagnosis has not yet been established in these subjects with persistent or recurrent symptoms (see Figure 1 of the original guideline document). Endoscopy is indicated for those patients who have no response to empiric acid suppression, those in whom symptoms progress during therapy, and those in whom symptoms recur after therapy is completed.

Whether endoscopy is used as an initial strategy or is performed after failure of empiric therapy, it remains controversial whether H pylori testing should be obtained. If biopsy specimens are obtained and are positive, H pylori should be treated. However, it is unclear whether H pylori treatment will result in symptomatic improvement of these patients with nonulcer dyspepsia.

UGI barium studies are not recommended in the evaluation of high-risk or low-risk patients with dyspepsia. Endoscopy is superior to UGI barium studies in light of its greater sensitivity/specificity and because biopsy specimens can be obtained or endoscopic therapy can be delivered if required. Most abnormal or equivocal findings on barium studies require upper endoscopic evaluation. Patients at high risk with negative barium UGI examinations may still benefit from endoscopy.

Gastric ulcers visualized on endoscopy should be adequately biopsied to exclude malignancy because gross endoscopic appearance of gastric ulcers is not sufficient

to exclude malignancy. If a UGI series shows a discrete crater in the duodenum as the only lesion, endoscopy is not usually indicated. However, if the clinical response to proper medical therapy is not prompt and sustained, endoscopy can help establish or exclude other possible conditions.

Biopsy of a duodenal ulcer is not routinely indicated, and endoscopy has no role in the usual follow-up of uncomplicated duodenal ulcer.

<u>Summary</u>

The controversy regarding the medical, economic, and quality-of-life risks and benefits comparing early (initial) endoscopy versus empiric medical management for patients presenting with dyspeptic symptoms continues despite multiple studies. Unfortunately the effectiveness of any single strategy has not yet been reproducibly proven in a randomized prospective, blinded clinical trial. Endoscopy remains the "gold standard" because of its diagnostic superiority and improved patient satisfaction in excluding organic lesions as a cause of the presenting symptoms.

As seen in Figure 1 of the original guideline document, a suggested algorithm is presented:

- Patients with alarm symptoms should undergo prompt endoscopy.
- In the absence of alarm symptoms, endoscopy or medical management may be considered.
- In the absence of risk factors, the superiority of initial medical management versus endoscopy has not been established.
- Regardless of which medical management approach is taken, the lack of response or the recurrence of symptoms warrants endoscopic evaluation.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for the diagnostic use of endoscopy.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnostic evaluation and management of dyspepsia

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Dec

GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of the <u>Journal of the American Society</u> <u>for Gastrointestinal Endoscopy</u>.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 23, 2005. The information was verified by the guideline developer on March 31, 2005.

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